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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,610	02/12/2001	Jonathan Stanley Harold Denyer	102199-100	3883

7590 05/03/2005

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/781,610

Applicant(s)

DENYER ET AL.

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,7-9,12,13,15-21,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21,39 and 40 is/are allowed.
- 6) ☒ Claim(s) 1-4,7-9,12,13 and 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments, see pages, 6-8, filed 8 February 2005, with respect to 1-4, 8, 9, 13, 15, 16-18 and 20 have been fully considered and are persuasive. The 102(e) rejections to Romick; 102(b) rejections to Castellano; and 103(a) rejections to Romick/Castellan of claims 1-4, 8, 9, 13, 15, 16-18 and 20 have been withdrawn.
2. Applicant's arguments to Wolf et al. filed 8 February have been fully considered but they are not persuasive. The device of Wolf et al. teaches all of the structural limitations of the Application claims. The Applicant argues that the electronic data carrier of Wolf is not removable from the drug vial. However, as seen in fig. 1, it clearly is removable.

### ***Claim Objections***

3. Claim 16 is objected to because of the following informalities: claim 16 depends on cancelled claim 14. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 13, and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 13 recites the limitation "the medication chamber" in line 3. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al. 5505195.

9. Wolf et al. teaches an electronic data carrier for use with a drug delivery apparatus removable from the drug delivery device, comprising a memory located within the electronic data carrier for holding treatment information concerning the use of the drug delivery apparatus in delivering a specified drug, and an output for transmitting treatment information to the drug delivery apparatus (col. 11, lines 41-58).

10. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. 5237989.

11. Anderson et al. teaches a drug delivery system comprising: a drug delivery apparatus, the apparatus having a medication chamber 48; and electronic input 28 arranged remotely from the medication chamber; an electronic data carrier removable from the drug delivery device containing treatment information and including an output for transmitting treatment information (see claim 5).

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-4, 7, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al.

14. Wolf et al. teaches a drug package comprising: a container 140 containing drugs; an electronic data carrier 110 removable from the container; wherein the data carrier is arranged to include at least one of the following items of treatment information: the dose of the drug to be delivered; the identity of the drug which is to be delivered; the expiry date of the drug which is to be delivered; the number of treatments available from the drug package; wherein the data carrier is arranged to supply drug treatment information to a drug delivery device a number of times corresponding to the number of treatments available (fig. 10, 1035); and wherein the data carrier includes a memory. It should be noted that Wolf et al. fails to teach a plurality of containers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a plurality of containers, since it has been held that mere duplication of the parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

### **Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM

  
GLENN K. DAWSON  
PRIMARY EXAMINER